2021 Call for Applications for ALS research projects

Deadline: May 13th, 2021 at 1.00 pm

General features

With this Call, AriSLA, the Italian Foundation for Research on ALS - Amyotrophic Lateral Sclerosis (in brief “AriSLA” or “the Foundation”) aims at selecting excellent research to promote knowledge on ALS and fight the disease.

The Call admits both Pilot and Full Grant Applications for projects on ALS research.

**Pilot Grants** concern research projects with highly innovative and original hypotheses, where preliminary data are either not available or to be consolidated. As such, they are intended to collect or strengthen preliminary data for subsequent larger scale funding.

Particularly for this type of Application, AriSLA Foundation encourages Applications from junior investigators and investigators who are new to the ALS field.

Only Single-centre Applications are admitted.

The duration of the proposed project is 1 year.

**Full Grants** concern research projects with a solid background and consistent preliminary data.

Applications can either be Single-centre or Multi-centre. The Principal Investigator (PI) is the scientific coordinator of the project, either in case of a Single-centre or a Multi-centre project. In case of a Multi-centre project, the synergy derived from Partners’ contribution to the achievement of the project objectives should be evident.

The duration of the proposed project can range from 1 to 3 years.

Both types of Applications may address basic or preclinical research areas or clinical observational studies. Applications based on clinical interventional studies are not admitted.

In order to be fundable, both types of Applications should be original and ground-breaking with respect to current science and of high scientific quality. Projects should demonstrate a strong potential to impact on disease understanding, diagnosis or treatment of ALS.

Projects that have already been fully funded by other Agencies are not eligible.

Awards are contingent upon availability of funds.

Eligibility Criteria

**Eligible Host Institutions**

Only research Applications submitted by investigators working in Italian non-profit Universities and Research Institutes, either public or private, performing research activities consistent with the statutory
purposes of the Foundation, are eligible. In case of Multi-centre studies, this applies to both the PI and the Partners, generally defined as Applicant.

The Host Institution declares that the Applicant is authorised to submit the Application on its behalf. By signing the General Information page (which must be attached to the Application by the PI, also on behalf of Partners, if any) the Host Institution shall undertake to respect any and all conditions under this Call for Applications and discharges AriSLA from any liability related to any breach of said conditions by the Applicant and/or by the Host Institution itself.

The Legal Representative of the Host Institution has to declare that the Host Institution will provide the necessary facilities and personnel to carry out the submitted research project. **If the Applicant is not holder of a permanent position, her/his salary needs to be provided through other means.**

**Investigators working in Host Institutions outside Italy** or in **for-profit organisations** can participate as Collaborators only, upon presentation of a **collaboration letter**, explaining the type of support to the research project.

**Eligible Applicants**

Applicants must demonstrate proven scientific competence, independence, and capability to self-manage the proposed project and must operate in the Host Institution for the entire duration of the Grant.

If the Applicant does not hold a permanent position, the Host Institution should be aware that the salary of the Investigator cannot be requested in the budget of the Application.

If the Application is successful, but the scientific independence of the Applicant is not clearly evident to the International Scientific Committee (ISC), the Committee may recommend funding, pending a statement by the Applicant’s Director (e.g., head of laboratory/department) stating that the results of the funded project will belong to the Applicant in the form of adequate authorship in any ensuing publications (last name/corresponding author).

Investigators are allowed to apply for a maximum of 2 Grants, and can be PI of 1 Application only, in response to this Call.

For Applicants of ongoing AriSLA projects that are not expected to end by December 31st, 2021, the following rules apply:

- a PI is not eligible to submit a new Application as PI, but can apply as Partner in one Multi-centre Application;
- a Partner of one ongoing project can apply for one new Grant, either as PI or Partner;
- a Partner of two ongoing projects is not eligible for the current Call.

**New application or Renewal Application by a former grantee**

The holder of a previously funded AriSLA project that will end by December 31st, 2021 may submit a New or a Renewal Application.
A “Renewal Application” is a new funding request based on data from a previously funded AriSLA Grant, while a “New Application” is a new funding request dealing with a different research topic.

Renewal Applications of previously funded Grants are encouraged, and the effective exploitation of the results obtained with the previous Grant will be matter of evaluation.

The “Renewal Application” of a previously funded Pilot Grant can only be submitted as Full Grant Application. The holder of a previously funded Pilot Grant may apply for another Pilot Grant as a “New Application” specifying the reasons of changing the research topic.

Revised Applications

Applicants who have submitted an Application to a previous AriSLA Call for Research Projects that was not funded may participate in this Call by submitting a “Revised Application”, modified in accordance with the comments received during the evaluation process. In this case, a reply to the issues raised by the reviewers should be reported in the box “Changes from previous revision”.

Only up to two resubmissions of a previously unsuccessful Application, not necessarily in consecutive years, are allowed.

Budget

Pilot Grant Applications are allowed to request a contribution up to €60,000.

Full Grant Applications are allowed to request a contribution up to a maximum of 80,000 €/year for a maximum of 3 years.

The budget description must be accurate, and every item must be justified.

AriSLA reminds all Applicants and their Institutions that funds are raised through many small individual donations and therefore AriSLA feels a special responsibility to oversee an appropriate allocation of funds.

Evaluation steps

Submitting the Application

Applications must be written in English and compiled following the specific guidelines (see "Application Guidelines 2021") which are an integral part of this Call.

Applications that are incomplete, lack any of the mandatory documents or do not comply with the requirements stated in this Call for Applications and pertinent Guidelines will not be accepted.

Applications have one-steps submission process and will be evaluated through two consecutive phases: Triage and Full Proposal Evaluation.

2021 Call for Applications
The Application has to be electronically submitted by **May 13th, 2021 at 1.00 pm** by the PI, by filling out all forms of the Pilot Grant or Full Grant Application. Forms are available on the AriSLA website, starting from March 26th, 2021.

**No hard copy of the online Application needs to be sent via email.**

**Triage and Full Proposal Evaluation**

Each accepted Application will be evaluated by the AriSLA ISC, in order to guarantee meritocracy, transparency and impartiality of the selection process.

The list of members of last year’s AriSLA ISC is reported on the AriSLA website ([Il Comitato Scientifico AriSLA 2020](https://www.arisl.org)). Additional experts may be involved if considered necessary.

**Procedure**

AriSLA staff and reviewers involved in the evaluation process are bound by strict confidentiality and conflict of interest rules defined by the Foundation. Grants will be awarded on a competitive basis.

Applications will be assessed by a two-step peer-review:

1) **Triage**

The AriSLA ISC will perform a remote evaluation of the following sections of the Application:

- Section I – General Information
- Section II – Project Information
- Section V – Applicant

During the Triage phase each Application will be independently evaluated by three reviewers of proven expertise in the field of the topic of the project, who will provide a brief written comment and a score. All Applications will be ranked based on the evaluation criteria reported below. The results of the Triage phase will be communicated to all PIs. In addition, the PIs of the excluded Applications will receive a report with the reviewers’ comments. It is anticipated that approximately up to the top-ranking 40 Applications will proceed to the second step.

2) **Full Proposal Evaluation**

The Applications selected for the Full Evaluation will be assigned to three independent reviewers of the AriSLA ISC, available to take part in the Consensus Meeting. During this phase, all Sections of the Application will be evaluated.

In addition to remote individual evaluations, the panel of reviewers involved in the second step will proceed to a comparative evaluation of the top-scoring Full Proposals during the Consensus Meeting, and all reviewers will score each Application. The outcome of the Consensus Meeting will be a final merit-based list.

Information on the evaluation process and outcomes of the Full Proposals will be provided to the interested PIs by the end of December 2021.
Reviewers’ AriSLA Guidelines for Triage and Full Proposal Evaluations are available on AriSLA’s website.

**Evaluation criteria**

**Pilot Grants**

Triage evaluation will be based on the following criteria.

1. **Innovation and originality** of the proposed project with regards to the current knowledge
2. **Quality and feasibility** of the scientific approach. The following parameters will be evaluated:
   - Relevance and significance for ALS
   - Rationale
   - Appropriateness of design and methods
   - Overall feasibility of the study.

Full proposal evaluation will be based on the following criteria.

- **Innovation** of the proposed project with regards to the current knowledge
- **Expected impact** of the results on the disease knowledge and treatment or any other influence on clinical management of patients; proximity to therapeutic development or to any other potential impact on patients of the proposed study; potential admissibility of results for intellectual property protection
- **Objectives** and **methodologies**: appropriateness of methods and analyses with respect to the aims of the study
- **Capability to successfully carry out the project**: ability of the Applicant to finalize the proposed research program according to the project duration and budget
- **Potential** of the expected results to be attractive for larger scale funding.

**Full Grants**

Triage evaluation will be based on the following criteria:

1. **Innovation and originality** of the proposed project with regards to the current knowledge
2. **Quality and feasibility** of the scientific approach; the following parameters will be evaluated:
   - Relevance and significance for ALS
   - Soundness of background and rationale
   - Robustness of the preliminary data
   - Appropriateness of design and methods
   - Experience of the Applicants in the field
   - Overall feasibility of the study

Full proposal evaluation will be based on the following criteria:

- **Strength of the background and rationale**
- **Availability of solid preliminary data** to support the research program and relevance of the project for ALS
- **Clarity of the objectives** and appropriateness of design and methods proposed to achieve them
• **Expected impact** of the results on the disease knowledge and treatment or any other influence on clinical management of patients; proximity to therapeutic development or to any other potential impact on patients of the proposed study; potential admissibility of results for intellectual property protection

• **Investigator experience and synergy with Partners (if any):** competence and scientific independence of the Applicants; complementarity and synergy among PI and Partners of Multi-centre studies

• Sound and effective exploitation of the **results derived from previously funded AriSLA Pilot/Full Grant** (if applicable).

The ISC will also review the budget, which may be reduced with respect to the original request.

In particular, care will be taken to avoid overlapping funding of scientific activities already supported by other Applicant’s grants, which must be accurately described in the appropriate section of the online Application.

**Awarding of research funds**

Awarded funds must be spent to accomplish the research for which they have been approved. AriSLA requires that the funds be used effectively and economically, and that the expenses be essential for the research for which the funds were awarded.

No funds will be awarded by AriSLA to any Host Institution until both parties have signed a specific agreement according to art. 3 of the D.P.R. 20th March 2003, n. 135.

AriSLA reserves the right to ask for a copy of the statute of the Host Institution and of the latest available balance sheet, as well as the acknowledgement of the legal status for all the investigators working for non-profit private organisations. AriSLA reserves the right to evaluate the compatibility of the statutory guidelines of the private Institutions on a case-by-case basis, with the aim of ensuring social benefit and of the financial reliability in order, if necessary, to dictate the conditions for the assignment/payment of the contribution.

AriSLA reserves the right to site visit the Host Institution before releasing any funds and/or at any time afterwards, during the grant period.

The release of funds is subject to the submission of all required documentation, as specified in the respective “**Application Guidelines_2021**” for Full and Pilot Grants and as requested by the AriSLA Offices.

**All costs allocated will be reimbursed upon administrative report of the expenses.**

In case of two- or three-year awards, recipients must provide a detailed a periodic administrative report in order to obtain the subsequent payment.

AriSLA reserves the right to cancel payments whenever a conflict arises regarding the stipulations contained in this Call for Applications, or stipulations specifically made by AriSLA to the Host Institution and/or to the Investigator.

**Code of Conduct for research integrity**

AriSLA adheres to the principles for a responsible conduct of research (RCR) reported by the European Code of Conduct for Research namely: reliability, honesty, respect, accountability
As such, the Foundation expects Applicants, Grantees and all research personnel involved at any level with the AriSLA research Applications or approved grants to strictly adhere to the highest standards of research conduct therein reported.

Dissemination of results of funded projects

AriSLA wants to ensure that new knowledge generated by its research funding will be widely disseminated and readily made available for the benefit of ALS patients. In particular, the Foundation reminds that the funded investigators have the obligation to:

- inform in advance about any publication and to acknowledge AriSLA for all publications arisen from the project;
- adhere to the Open Access Policy;
- be compliant with the European General Data Protection Regulation no. 679/2016 as well as with any other applicable local law;
- submit Final Scientific Reports at the end of the project.

For further details please refer to AriSLA Dissemination Policy, “Policy sulla Comunicazione e Disseminazione della Ricerca”.

Intellectual property

AriSLA mission is to translate research results into therapies and to make them available to patients. To achieve this goal, the Foundation requests the funded investigators to undertake any necessary steps to ensure adequate valorisation and exploitation of the research outcomes.

For further information please refer to AriSLA Intellectual Property Rights Policy, “Policy sulla Proprietà Intellettuale”.

Adoption of an AriSLA funded project

AriSLA claims the right to promote the “adoption” of the funded projects by third parties; therefore, it is recommended to consult the AriSLA Projects Adoption Policy, “Policy per l’Adozione dei Progetti di AriSLA”.

Privacy of personal data

According to the Current Law, General Data Protection Regulation (EU) 2016/679 (GDPR) and D.Lgs 196/2003, regulating the protection of natural persons in relation to the processing of personal data, AriSLA and the Host Institution will be considered as being autonomous data controllers of the personal data to be processed under the Application.
The Host Institution is allowed to indicate the personal data of the Applicant as well as of any other researcher involved in the Application (Key Personnel and Collaborators not actively involved in the research project), on the condition that the Host Institution: (i) has provided the involved researchers with the attached information (INFORMATIVA SUL TRATTAMENTO DEI DATI PERSONALI) (ii) has thereby gathered the relevant consents; and (iii) has undersigned the General Information page of the Application ensuring that the above conditions have been respected. AriSLA shall, at any time, have the right to examine such documents (information to data subjects and declaration of consent) at the Host Institution location. The Host Institution shall deliver any document, according to AriSLA’s request.

**Assistance**

For any information about the Call or about the Application Form compilation please contact:

*E-mail Help Desk:* bandi@arisla.org

*Phone Help Desk:* at the phone number +39 02.20.24.23.90 from 9.00 am to 5.00 pm (Mon-Fri).
INFORMATIVA SUL TRATTAMENTO DEI DATI PERSONALI
ex art. 13 del Regolamento UE 2016/679

Ai sensi dell’art. 13 del Regolamento UE 2016/679 (GDPR) e a tutela del Suo diritto alla protezione dei Dati personali la Fondazione Italiana di ricerca per la SLA - Sclerosi Laterale Amiotrofica (AriSLA) intende fornirle le seguenti informazioni.

TITOLARE DEL TRATTAMENTO

TITOLARE del trattamento dei Suoi Dati personali è la Fondazione Italiana di ricerca per la SLA - Sclerosi Laterale Amiotrofica (AriSLA), con sede in Via Poerio, 14 - 20129 Milano (C.F.: 97511040152), in persona del legale rappresentante pro tempore, avente i seguenti dati di contatto:

- email: privacy@arisla.org
- Tel: 02.20242390

Il Titolare ha nominato un Responsabile del trattamento dei dati o Data Protection Officer (DPO), l’avv. Michela Maggi, contattabile ai seguenti indirizzi: michela.maggi@milano.pecavvocati.it e mmaggi@maggilegal.it.

FINALITÀ DEL TRATTAMENTO E DATI TRATTATI

I Suoi dati quali nome, cognome, indirizzo di residenza, indirizzo di domicilio, codice fiscale, e-mail, telefono, esperienze professionali, istruzione, formazione, titoli, pubblicazioni, saranno trattati dal Titolare per le seguenti finalità:

A) gestione della procedura concorsuale o selettiva, per l’eventuale erogazione di contributi per il finanziamento di progetti di ricerca scientifica, per la gestione delle graduatorie (ove previste nel bando), nonché l’invio di informazioni relative al predetto bando di concorso;

B) in caso di aggiudicazione, per l’assunzione o il conferimento dell’incarico, per la gestione del progetto di ricerca e l’adempimento degli obblighi di legge correlati;

C) in caso di aggiudicazione, per la divulgazione del progetto e dei dati del Ricercatore responsabile del progetto (“Principal Investigator, PI” nel caso di Ricercatore responsabile per Progetto singolo o del coordinatore di un Progetto multicentrico, o “Partner”, nel caso del Ricercatore responsabile di un altro Centro partecipante al Progetto multicentrico) sia mezzo stampa che sul sito internet e sui social network del Titolare.

BASE GIURIDICA DEL TRATTAMENTO

La base giuridica per le finalità di cui alle lettere A) e B) è l’esecuzione di misure precontrattuali, l’esecuzione del contratto e l’adempimento di obblighi legali ex art. 6, comma 1, lettera b) e lettera c) GDPR. La base giuridica per la finalità di cui alla lettera C) è il perseguimento del legittimo interesse del Titolare del trattamento ex art. 6, comma 1, lettera f) GDPR.

I Suoi dati particolari saranno trattati esclusivamente per consentire ad AriSLA di fornire il supporto necessario ai candidati con disabilità e di erogare i servizi necessari al fine di consentire la loro partecipazione ex art. 9, comma 2, lett. b) GDPR.

NATURA OBBLIGATORIA O FACOLTATIVA DEL CONFERIMENTO

Il conferimento dei Suoi Dati personali è indispensabile affinché il Titolare possa compiere le attività necessarie per le finalità di cui alle predette lettere A), B) e C). Ne consegue che il mancato conferimento dei
Suoi Dati per le finalità di cui sopra comporterà l’oggettiva impossibilità di partecipare al bando di concorso organizzato dal Titolare del trattamento.

**MODALITÀ DEL TRATTAMENTO**

Il trattamento dei Suoi dati personali sarà effettuato con le modalità manuali ed informatizzate, anche con l’ausilio di mezzi elettronici o comunque automatizzati, nei modi e nei limiti necessari per perseguire le predette finalità e con l’adozione delle misure di sicurezza di cui all’art. 32 del GDPR da parte del Titolare e dei soggetti quali dipendenti, collaboratori o terzi all’uopo designati, mediante atto scritto, persone autorizzate o responsabili esterni del trattamento e tenuti ad operare nei limiti e nell’osservanza delle istruzioni impartite dal Titolare.

Pertanto, il trattamento sarà svolto direttamente dal Titolare, con la collaborazione di soggetti all’uopo autorizzati e degli eventuali responsabili esterni, nominati, ove necessario, per specifiche operazioni.

**DESTINATARI DEI DATI PERSONALI**

Il Titolare del trattamento non diffonderà i Suoi dati personali.

I Suoi dati personali non saranno diffusi per uno scopo diverso da quello per il quale sono stati raccolti/conseguiti, ma potranno essere pubblicati sul sito internet e sui social network del Titolare del trattamento, riprodotti nel materiale informativo predisposto dallo stesso Titolare, e comunicati:

i. al personale del Titolare del trattamento, con particolare riferimento ai dipendenti e collaboratori che si occupano delle specifiche attività nell’ambito delle quali viene operato il trattamento dei dati, designati autorizzati al trattamento mediante atto scritto;

ii. a soggetti terzi, titolari autonomi o nominati Responsabili o sub responsabili del trattamento, con cui vengono conclusi specifici accordi di riservatezza, quali a titolo esemplificativo e non esaustivo revisori, esperti valutatori o consulenti, terzi che si occupano dello sviluppo e manutenzione degli strumenti informatici o che forniscono prestazioni o servizi legati alle finalità sopra indicate.

L’elenco completo ed aggiornato dei responsabili del trattamento, nonché degli altri soggetti a cui i dati personali potranno essere comunicati è disponibile presso la sede del Titolare e potrà essere liberamente consultato su richiesta.

**LUOGO DI TRATTAMENTO E TRASFERIMENTO DEI DATI**

I trattamenti hanno luogo presso la predetta sede del Titolare del trattamento e presso i soggetti terzi individuati.

I dati personali sono conservati all’interno della fondazione e su server ubicati all’interno dell’Unione Europea. Resta in ogni caso inteso che il Titolare, ove si rendesse necessario, avrà facoltà di trasferire i dati personali anche in Paesi extra-UE. In tal caso, il Titolare assicura sin d’ora che il trasferimento dei dati extra-UE avverrà in conformità alle disposizioni di legge applicabili. In assenza di decisione di adeguatezza della Commissione Europea, eventuali trattamenti di dati personali in Paesi non UE saranno possibili solo in presenza di garanzie adeguate di natura contrattuale o pattizia, fra cui norme vincolanti d’impresa e clausole contrattuali tipo di protezione dei dati, da parte dei Titolari e Responsabili coinvolti.

In mancanza di una decisione di adeguatezza o di altre misure adeguate come sopra descritte, il trasferimento e il trattamento dei dati personali al di fuori dell’Unione Europea sarà effettuato solo previo consenso dell’interessato.
PERIODO DI CONSERVAZIONE DEI DATI PERSONALI:

I Suoi Dati Personali saranno conservati solo per il tempo necessario all’espletamento di tutte le attività relative alle procedure di selezione dei progetti e una volta completati, per tutto il tempo strettamente necessario al perseguimento delle finalità sopra indicate, salvo eventuali termini di conservazione previsti da leggi o regolamenti o salvo che gli stessi debbano essere conservati al fine di adeguare un obbligo di legge e/o per far valere un diritto in sede giudiziaria.

DIRITTO DI ACCESSO AI DATI PERSONALI ED ALTRI DIRITTI

Lei potrà far valere i propri diritti come espressi dall’art. 15, 16, 17, 18, 20 e 21 del Regolamento UE 2016/679 (GDPR), rivolgendosi al Titolare ai dati di contatto sopra indicati.

In particolare il Titolare La informa dell’esistenza dei seguenti diritti:

- ottenere la conferma dell’esistenza o meno di dati personali che La riguardano, anche se non ancora registrati, e la loro comunicazione in forma intelligibile;
- ottenere l’aggiornamento, la rettificazione ovvero, quando vi ha interesse, l’integrazione dei dati incompleti e la limitazione del trattamento nei casi previsti dall’art. 18 GDPR;
- ottenere la cancellazione dei dati personali e la trasformazione in forma anonima o il blocco dei dati trattati in violazione di legge, compresi quelli di cui non è necessaria la conservazione in relazione agli scopi per i quali i dati sono stati raccolti o successivamente trattati;
- opporsi, in qualsiasi momento, per motivi connessi alla sua situazione particolare, al trattamento dei dati personali che La riguardano ai sensi dell’articolo 6, paragrafo 1, lettere e) o f), al trattamento dei dati per finalità di marketing diretto, compresa la profilazione;
- ricevere in un formato strutturato, di uso comune e leggibile da dispositivo automatico i dati forniti al Titolare, nonché, se tecnicamente fattibile, trasmetterli ad altro Titolare senza impedimenti;
- revocare il consenso prestato in qualsiasi momento senza pregiudicare la liceità del trattamento basato sul consenso prestato prima della revoca, nei casi previsti dalla legge;
- proporre reclamo all’Autorità di controllo competente;
- ottenere l’attestazione che le operazioni di cancellazione, rettifica e limitazione sono state portate a conoscenza, anche per quanto riguarda il loro contenuto, di coloro ai quali i dati sono stati comunicati o diffusi, salvo che tale adempimento si rivelì impossibile o comporti un impiego di mezzi manifestamen
te sproportionato rispetto al diritto tutelato;
- non essere sottoposto a una decisione basata unicamente sul trattamento automatizzato, compresa la profilazione, che produca effetti giuridici che lo riguardano o che incida in modo analogo significativamente sulla sua persona.

Milano,